

EFCC's Feedback on the Inception Impact Assessment on the Revision of EU legislation on registration, evaluation, authorisation and restriction of chemicals (REACH)

The European Federation for Construction Chemicals (EFCC) represents European construction chemicals companies and national member associations, representing raw materials producers and formulators of finished products, including SMEs, across the European Union. EFCC welcomes the opportunity to participate in the public consultation on the Inception Impact Assessment for REACH.

The construction chemicals industry in Europe continues to be fully supportive of improving REACH, as the foundation of managing the risks associated with construction chemicals. Recent reviews and fitness checks have identified opportunities to achieve better consistency and eliminate duplication, solve implementation issues, clarify data requirements to minimise animal testing, digitalise communication regarding the safe use of chemicals in the supply chain and improve enforcement across the European Union.

Generic approach to risk management

Regulating chemicals on the basis of their hazard only, is overly simplistic and risks removing chemicals from the EU market that have high societal, environmental and economic benefits. Chemicals should be regulated on the basis of sound science reflecting both hazard and exposure (i.e. safe use). A 'generic risk management' approach based on hazard should be applied in a targeted way, only to substances and/or uses where adequate control of risks has not been demonstrated.

Essential Use

EFCC would like to express their concern that what might be recognised as an "essential use" will be of a highly political nature with unavoidable socio-economic consequences. A generic definition-based approach to what is essential, is not a solution that can ensure sufficient clarity and predictability to industry, professional users and consumers. The value chemical substances or products could bring to society should be taken into account. A chemical substance or product when looked at in isolation, might not be considered essential. However, from a sustainability perspective it could bring value in increasing durability of a product or article. So we advocate applying a life cycle approach to evaluating essential use taking social, economic as well as health & environmental aspects into account. Moreover, "essentiality" should be considered to be temporary to allow for the COM to realise its ambitions for innovation.

Combination effects of chemicals and Mixture Assessment Factor (MAF)

The concern on possible combination effect of chemicals should focus on unintentional, combined exposures, not on situations where simultaneous exposure is already known, such as when placing on the market of mixtures as well in in an occupational safety context.

EFCC is not in favour of the introduction of a generic or fixed MAF, to be applied to all chemicals. A blanket MAF would be arbitrary and not based on sound science, covering largely hypothetical exposures and risks, rather than realistic scenarios and could result in the phasing out of non-hazardous products containing hazardous components at concentrations below both effect or classification levels.

A generic application of a MAF would result in unnecessary compliance activities that will ultimately not achieve the regulatory goals. Thus, MAFs, when introduced, should be proportional, targeted, and based on a sound scientific knowledge and, in addition, should allow for specific evidence-based refinement. MAF could be relevant to unintentional mixtures and therefore should only be applied to the calculated Risk Characterisation Ratios (RCRs). Application of a MAF of 5 to the calculated RCR, would mean a five times higher exposure, and result in a gross overestimation of the risk.

Simplifying communication in the supply chains

Communication on how chemicals can be used in safely along the supply chain is key to ensure proper risk management by e.g. formulators. EFCC members play a key role as formulators, as on one hand they need to ensure the safe use both of the chemicals (substances and mixtures) they use to manufacture mixtures and other hand ensure the safe use of the formulations they place on the market. EFCC continues to be committed to contribute to Use Maps and input parameters for workers exposure assessment (SWED) files, working closely with ECHA and other downstream users.

A uniform exchange standard (e.g. XML-based) for conveying relevant safety data electronically along the supply chain could be useful, if simple and user-friendly interface solutions are developed, that would facilitate the use of the electronic exchange of data along the supply chain. However, any decision regarding the strategy to introduce new digital solutions in the market can only be taken on the basis of a favourable assessment of the costs versus the benefits.

'One substance one assessment'

The concept of 'one substance one assessment' could only be appropriate if applied to hazard assessment, as it could streamline the assessment process and seemingly different outcomes due to hazard assessments carried out at different times by different bodies, under different legislations could be avoided. In our view, risk assessment is specific to uses and expertise should remain with the existing responsible agencies.

The current restriction process is too slow

We recognise that the generation of an Annex XV dossier is a burden to the Authorities. This illustrates that a proper assessment is needed for complex situations. If substances did not present a benefit to society, the decision would be easy, but most of the time there is a good justification for the use of certain hazardous chemicals.

Industry has a wealth of knowledge and expertise and could help being more involved. Perhaps Industry as a whole (e.g. also Downstream Users) could be more engaged with the concerned Authorities, be tasked to conduct activities currently in the hands of the Authorities to relieve them, but under their control. This could be a way to lower the burden for Authorities, speed up the evaluation while maintaining a proper scientific assessment.

Enforcement

Proper enforcement is certainly desirable to ensure a level playing field between EU-made products or articles and imported products or articles from outside the EU.

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